IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

CHARLESTON DIVISION

IN RE: C. R. BARD, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**MDL NO. 2187**
THIS DOCUMENT RELATES TO PLAINTIFFS:	
Linda Rizzo and Ronald Rizzo	**2:10-cv-01224**
Wanda Queen and Greg Queen	**2:11-cv-00012**
Carolyn Jones	**2:11-cv-00114**
Donna Cisson and Dan Cisson	**2:11-cv-00195**

DEFENDANT C. R. BARD, INC.'S MEMORANDUM OF LAW IN OPPOSITION TO PLAINTIFFS' MOTION *IN LIMINE* NO. 1 – 510(K) CLEARANCE OF THE AVAULTA PRODUCTS BY THE UNITED STATES FOOD AND DRUG ADMINISTRATION ("FDA"), OR LACK OF FDA ENFORCEMENT

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This Court has already determined that evidence of Bard's compliance with FDA requirements may be relevant to Plaintiffs' state law claims.[1] Nevertheless, Plaintiffs now seek to preclude Bard from offering regulatory evidence suggesting that its Avaulta products are safe and effective and that Bard acted reasonably in designing its Avaulta products and bringing them to market. (Plaintiffs' Motion in Limine No. 1 ("Motion").) Plaintiffs' Motion should be denied because Plaintiffs' claims put the safety of the Avaulta products and the reasonableness of Bard's conduct directly at issue. Bard is therefore entitled to present, and it imperative that the jury hear and understand, the full and accurate story of how the Avaulta products came to market: to wit, that Bard engaged in and fully complied with the statutorily-required regulatory process mandated by the U.S. Food and Drug Administration ("FDA"), pursuant to which the FDA cleared and made express determinations about the device's safety and efficacy, and without which Bard could and would not have sold the device in the United States.

Bard sold the Avaulta Systems in the United States only after complying with the FDA's 510(k) premarket requirements. In accordance with these requirements, Bard's submission to the FDA included information concerning the device's intended use, extensive testing supporting the device's safety, the device's labeling, information on predicate products, design information, and performance data. *See* 21 C.F.R. §§ 807.87, 807.9. At the end of this process, Bard was able to sell the product only because the FDA made a determination that the Avaulta System was "substantially equivalent" to devices already on the market and in clinical use, which means the FDA found that the Avaulta System was at least "as safe and effective" as a predicate device. *See* 21 U.S.C. § 360c(i)(1)(A). After the Avaulta System came to market, Bard continued to comply with FDA requirements by, *inter alia*, filing additional Special 510(k)s with the FDA and

[1] *See, e.g.*, Doc. No. 272, p. 18 (Case 2:11-cv-00195).

reporting adverse events. It is undisputed that the FDA never took any enforcement action against Bard in relation to its Avaulta Systems. As Plaintiffs' regulatory expert witness has testified, "I'm not aware of any [enforcement action], . . . I have not seen any enforcement action and I have no reason to believe there's an enforcement action." (*See* Deposition of David Kessler, M.D. at 270:10-18; 271:4-18.)

As discussed below, the Food, Drug and Cosmetic Act ("FDCA"), federal regulations, and the FDA's own statements demonstrate that the FDA reviewed Bard's Avaulta products for safety and efficacy as part of the 510(k) review process. Evidence of Bard's compliance with these and other government requirements is relevant and admissible to rebut Plaintiffs' claim that Bard was negligent in designing the Avaulta products, in bringing them to market, and in failing to warn of their alleged dangers, as well as to rebuff Plaintiff's strict liability claims, which also turn on the reasonableness of Bard's conduct and the safety of its products. Evidence of Bard's 510(k) clearance and compliance with FDA regulations is indisputably relevant. Further, Bard would be severely prejudiced if this evidence were precluded because the jury will not have a complete and accurate picture of the regulatory framework pursuant to which Bard did—and was required to—bring its product to market. Accordingly, this Court should deny Plaintiffs' Motion and allow Bard to introduce evidence showing that the FDA cleared Bard's Avaulta System for market via the 510(k) pathway and never took any enforcement action against Bard in relation to its Avaulta Systems.

I. FDA CLEARANCE OF THE AVAULTA SYSTEMS FOR MARKET UNDER THE § 510(K) PROCESS SHOWS THAT BARD ACTED REASONABLY IN BRINGING THE DEVICES TO THE MARKET AND THE FDA FOUND THE DEVICES WERE SAFE AND EFFECTIVE.

According to the FDA, every 510(k)-cleared product receives safety and efficacy review. This coupled with the FDA's specific findings about the Avaulta System, show the error in Plaintiffs' premise that the FDA never reviewed the safety or efficacy of the Avaulta products.

A. FDA has broad regulatory and enforcement authority over medical devices.

Under the FDCA, the FDA is given a very broad and exclusive authority to regulate all medical devices. The right to enforce the FDCA, promulgate regulations, and enforce those regulations rests exclusively with the FDA. *See Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 349 n.4 (2001). The FDA has enforcement authorities that the agency can and will use if it believes that a medical device poses a risk to patient health. Consistent with FDA's exclusive power to enforce the FDCA, FDA has the authority to investigate violations of the Act, and to impose sanctions, including "injunctive relief, 21 U.S.C. § 332, civil money penalties, 21 U.S.C. § 333(f)(1)(A), seizure of the device, 21 U.S.C. § 334(a)(2)(D), and criminal prosecution, 21 U.S.C. § 333(a), 18 U.S.C. § 1001.

B. FDA makes a safety and efficacy finding about every medical device cleared under the § 510(k) process.

The 510(k) process is a robust review of safety and efficacy that has been in place since the Medical Device Amendments of 1976 ("MDA"), which "applied safety and effectiveness safeguards to new devices."[2] To improve the regulation of medical devices and strengthen the MDA, in 1992 the FDA amended medical device regulations governing procedures for premarket notification in order to conform to provisions of the Safe Medical Devices Act of 1990 ("SMDA"). These amendments included 21 C.F.R. § 807.100,[3] which provides that the FDA will only determine that a product is substantially equivalent under the 510(k) process if the device has the same technological characteristics of a predicate device or data is submitted demonstrating that "**the device is as safe and as effective as a legally marketed device**" and the technological differences "do no raise different questions of safety and effectiveness." As the

[2] "Regulatory Information: Legislation" available on the FDA website at http://www.fda.gov/RegulatoryInformation/Legislation/default.htm (last accessed on June 17, 2013). A true and correct copy of this document is annexed hereto as **Exhibit A**.

[3] A true and correct copy of this regulation is annexed hereto as **Exhibit B**.

FDA has recently explicitly explained, "[s]afety and effectiveness factor into both parts of this review standard." [4] Thus, in the FDA's own words, "substantial equivalence" means "that the new device is at least as safe and effective as the predicate device on which it was based." [5]

On their face, the statute that created the § 510(k) pre-market notification process, FDA regulations, and FDA Guidance documents confirm that FDA makes an affirmative safety and efficacy decision about every medical device it clears for market.[6] Specifically, 21 U.S.C. § 360c(i)(1)(A) makes "safety and efficacy" part of the standard of review required for § 510(k) clearance. Under this process, a device may be marketed only if the manufacturer establishes that the new device is "substantially equivalent" to a predicate device that is already legally on the market, and the new device is substantially equivalent only if it is at least "as safe and effective" as the predicate device. 21 U.S.C. § 360c(i)(1)(A). In fact, the FDA has recently stated in a publicly released Guidance Document that "the principles of safety and effectiveness underlie the substantial equivalence determination in every 510(k) review."[7] Similarly, the FDA's Center for Devices and Radiological Health describes the current 510(k) process as "a multifaceted premarket review process that is expected to assure that cleared devices . . . provide reasonable assurance of safety and effectiveness . . . ."[8] Moreover, Bard has submitted evidence from the Former Director of the FDA's Office of Device Evaluation and other expert witnesses

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[4] FDA Guidance: The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)] at 6-7 (December 27, 2011). A true and correct copy of this document is annexed hereto as **Exhibit C**.

[5] "Premarket Notification (510k)" available on the FDA website at http://www.fda.gov/medicaldevices/deviceregulationandguidance/howtomarketyourdevice/premarketsubmissions/premarketnotification510k/default.htm (last accessed June 17, 2013). A true and correct copy of this document is annexed hereto as **Exhibit D**.

[6] *See also* Bard's Motion in Limine #3—Motion to Preclude Any Evidence or Argument Criticizing the U.S. Food and Drug Administration's 510(K) Clearance and Monitoring Process. To be clear, Bard is not arguing that its 510(k) clearance shows Plaintiffs' claims are expressly preempted, as this Court has already ruled on that issue.

[7] *See* Exhibit C at 6. Thus, while acknowledging that the PMA and 510(k) processes utilize different evidentiary standards, "in both cases FDA's review decision reflects a determination of the level of control necessary to provide a 'reasonable assurance of safety and effectiveness.'" *Id.* at 7.

[8] *See* 510(k) Working Group Preliminary Report and Recommendations, CDRH Preliminary Internal Evaluations at 34 (Aug. 2010). For the Court's convenience, a true and correct copy of this document is annexed hereto as **Exhibit E**.

demonstrating that the 510(k) process does address safety and effectiveness, and that for a product to be cleared, it must be as safe and effective as the predicate devices. (*See* Expert Reports of Donna-Bea Tillman at 3-12, 46 and Merry Lee Bain at 7-11.)

C. The FDA determined that all surgical meshes are Class II devices that must enter the market via the 510(k) pathway.

The overwhelming majority of medical devices (*i.e.* 98%) enter the market pursuant to the 510(k) pathway. Bard did not choose to enter the market through the 510(k) regulatory process; rather, the FDA, via federal regulation, determined that all surgical mesh products were Class II devices subject to the 510(k) process. *See* 21 C.F.R. § 878.3300 (classifying surgical mesh as a Class II device).[9] FDA regulations require that a manufacturer submit certain information as part of the 510(k) process. *See* 21 C.F.R. §§ 807.87, 807.92. Moreover, in 1999, the FDA issued a Guidance Document regarding the specific information surgical mesh manufacturers should provide in their 510(k) submissions.[10] This Guidance requires that manufacturers submit numerous types of testing results, labeling, performance data, specification of all material components of the device, information regarding how the device is manufactured, and "[s]ummary of information regarding safety and effectiveness."

D. The Avaulta devices went through the 510(k) process, and the FDA made specific safety and efficacy findings.

It is undisputed that Bard's Avaulta products went through the FDA's 510(k) process, and that Bard submitted testing, labeling, design, and specifications of the devices. In making this submission, Bard precisely followed the FDA's 1999 Guidance for surgical mesh 510(k)s and informed the FDA of its reliance on that guidance. The FDA's own review of Bard's 510(k)

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[9] The FDCA explains that Class II devices are those "which cannot be classified as a class I devices because the general controls by themselves are insufficient to provide reasonable assurances of the safety and effectiveness of the device." 21 U.S.C. § 360c(A)(1)(B).

[10] CDRH, "Guidance for the Preparation of a Premarket Notification Application for a Surgical Mesh," (Mar. 2, 1999). A true and correct copy of this Guidance document is annexed hereto as **Exhibit F**.

submission for it Avaulta products further removes any doubt that the safety and efficacy of the device was thoroughly reviewed.[11] The memorandum created by the FDA scientists who reviewed the application shows that they thoroughly analyzed the "safety data" and "effectiveness data" for both the Avaulta products and the predicate devices. (Exh. G at 124-140.) The reviewers noted that Bard conducted testing in accordance with the FDA's surgical mesh guidance and Blue Book memorandum on biocompatibility testing, concluding that

> The subject device's components, i.e., polypropylene mesh and porcine collagen, have been adequately assessed via biocompatibility determinations for safety and via physical strength and characterization assessments for prediction of effectiveness. **The product is substantially equivalent with respect to predicate surgical meshes for safety and effectiveness.**

(*Id.* at 135, 137.) Accordingly, because "the device is technologically, safety and effectiveness-wise-substantially equivalent to predicate surgical mesh products," the reviewers did not require any additional information from Bard. (*Id.* at 138-39.)

II. BARD'S COMPLIANCE WITH FDA REGULATIONS IS UNDENIABLY RELEVANT TO PLAINTIFFS' STRICT LIABILITY, NEGLIGENCE, AND PUNITIVE DAMAGES CLAIMS.

As this Court has already recognized, evidence regarding Bard's compliance with FDA regulations in its commercialization and marketing of the Avaulta products is indisputably relevant to Plaintiffs' product liability claims, and Bard is entitled to present such evidence in defense of these claims. Courts from around the country have consistently allowed evidence of a medical device or pharmaceutical manufacturer's compliance with FDA regulations in product liability lawsuits. *See, e.g., Hines v. Wyeth*, CIV.A. 2:04-0690, 2011 WL 2730908 (S.D.W. Va. July 13, 2011) (allowing both parties to offer evidence of compliance with relevant industry and government standards to demonstrate the reasonableness of defendants' conduct and the safety of

[11] A true and correct copy of Bard's Avaulta Plus and Solo 510(k) submission and the FDA's reviewer's memorandum obtained pursuant to a Freedom of Information Act Request is attached hereto as **Exhibit G**.

prescription drugs).[12] The Georgia Supreme Court[13] has spoken conclusively on the admissibility of a party's compliance with federal standards or regulations in product liability lawsuits:

> Under the risk-utility test**, compliance with federal standards or regulations is a factor for the jury to consider in deciding the question of reasonableness,** that is, whether the product design selected was a reasonable one from among the feasible choices of which the manufacturer was aware or should have been aware. It does not render a manufacturer's choice of design immune from liability. **That is not to say that evidence of such compliance is not significant, for it is. But, instead of acting as an impenetrable shield from liability, compliance, more appropriately, is to be a piece of the evidentiary puzzle.**

Doyle v. Volkswagenwerk Aktiengesellschaft, 481 S.E.2d 518, 521 (Ga. 1997).

Here, the fact that Bard submitted a 510(k) premarket notification with a plethora of information regarding its product's design and labeling and the FDA cleared the 510(k) submission without asking for additional information is direct evidence that Bard acted

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[12] *See also Salmon v. Parke, Davis & Co*., 520 F.2d 1359, 1362 (4th Cir. 1975) (noting that in North Carolina, as elsewhere, compliance with federal laws and regulations concerning a drug is pertinent to liability); *Taylor v. Mooney Aircraft Corp.,* 464 F. Supp. 2d 439, 451 (E.D. Pa. 2006) (applying Georgia law and considering manufacturer's compliance with federal regulations as evidence that manufacturer did not breach duty to warn); *Dorsey v. Honda Motor Co. Ltd*., 655 F.2d 650, 656 (5th Cir. 1981) ("Generally speaking, compliance with regulatory standards may be admissible on the issue of care"), *reh'g denied and opinion modified*, 670 F.2d 21 (5th Cir. 1982); *Strum v. Depuy Orthopaedics, Inc*., No. 11L009352, Order on Plaintiffs' Motion in Limine #3 (Ill. Cir. Ct. Cook Cnty. 2013) (denying plaintiff's motion to exclude evidence of the defendant device manufacturer's compliance with the 510(k) clearance process and other FDA regulations); *Elliott v. Brunswick Corp.,* 903 F.2d 1505, 1508 (11th Cir. 1990) (finding that a manufacturer's compliance with industry standards and federal regulations are probative to its liability for its design of allegedly defective products); *In re Guidant Corp. Implantable Defibrillators Prod. Liab. Litig*., MDL 05-1708 DWF/AJB, 2007 WL 1964337 (D. Minn. June 29, 2007) (allowing testimony as "as to the general nature of the approval and regulatory process including compliance with FDA regulations and guidelines, the FDA's general expectations with respect to testing and marketing of new products"); *Block v. Woo Young Med. Co. Ltd*., CIV. 09-1332 JRT/JJK, 2013 WL 1314449 (D. Minn. Mar. 28, 2013) (applying North Carolina law and allowing testimony regarding the FDA's approval and regulatory process); *Garay v. Missouri Pac. R.R*., 60 F. Supp. 2d 1168, 1174 (D. Kan. 1999) (denying Plaintiffs' motion in limine to exclude evidence of compliance with regulatory standards, noting that such evidence is relevant to the degree of care exercised by the defendants and the feasibility of alternative designs); *Mazur v. Merck Co*., 742 F. Supp. 239, 247 (E.D. Pa. 1990) ("compliance with an FDA regulation may establish that the manufacturer met the appropriate minimum standards of due care."); *Contini v. Hyundai Motor Co*., 840 F. Supp. 22, 24 (S.D.N.Y. 1993) (noting that compliance with regulatory standards is relevant and persuasive evidence in a product liability case); *Hartfield v. Sandoz-Wander, Inc*. 124 Ill. App. 3d 780, 787 (Ill. App. 1984) ("[E]vidence of compliance with Federal government standards is relevant in a strict tort liability case both on the issue of whether a product is defective and whether the defective condition is unreasonably dangerous"); *Rader v. Teva Parental Meds, Inc*., 795 F. Supp. 2d 1143, 1149 (D. Nev. 2011) ("compliance with product safety regulations is relevant and admissible on the question of defectiveness"); *see also* Restatement (Third) of Torts: Prod. Liab. § 4 ("a product's compliance with an applicable . . . administrative regulation is properly considered in determining whether the product is defective").

[13] This Court has ruled that Georgia substantive law applies to the product liability claims of Ms. Cisson and Ms. Rizzo.

reasonably—the key inquiry under Plaintiffs' negligence and strict liability claims. Bard is not asserting that its 510(k) clearance and lack of FDA enforcement completely absolves it of liability; rather, as courts in Georgia and around the country have recognized, such evidence is undeniably probative to the negligence and strict liability claims asserted by Plaintiffs.

Moreover, as explained in Bard's Motions for Partial Summary Judgment on Punitive Damages, compliance with federal regulations is also undeniably relevant to Plaintiffs' punitive damages claims. As numerous courts have held, punitive damages are generally not appropriate when a manufacturer complies with federal regulations and standards.[14] Because this Court has ruled that Plaintiffs can introduce evidence regarding Bard's liability for punitive damages during the initial trial on compensatory damages, it would be fundamentally unfair to prevent Bard from defending itself against this claim and rebutting evidence produced by Plaintiffs by showing that punitive damages are not warranted due to its compliance with federal regulations.

Plaintiffs' reliance on *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996) is misplaced for several reasons. (*See* Motion at 3-4.) As an initial matter, the Court in *Lohr* held only that claims against a manufacturer of a Class II device were not preempted; it never held that evidence of compliance with the 510(k) process was either irrelevant or inadmissible to a product liability claim. *See Lohr*, 518 U.S. at 486-503. Second, while the *Lohr* decision noted several differences between the 510(k) and PMA regulatory processes, the Supreme Court in a more recent decision clarified that, despite these differences, both processes are used "to ensure both that medical

[14] *See, e.g., Riley v. Ford Motor Co*., No. 2:09-cv-148-KS-MTP, 2011 WL 2938107, at *6 (S.D. Miss. 2011) (noting defendant "complied with all applicable government safety regulations" in finding punitive damages not to be warranted); *Mims v. Wright Med. Tech., Inc*., No. 1:11-cv-213-TWT, 2012 WL 1681810, at*5 (N.D. Ga. May 11, 2012) (granting summary judgment on punitive damages claim, noting the medical device manufacturer had to comply with federal regulations in order to sell its medical device).

devices are reasonably safe and effective . . . ." *Buckman*, 531 U.S. at 349-50.[15] Finally, the 510(k) process described in *Lohr* was not the same 510(k) process that existed when Bard's Avaulta products were cleared by the FDA in 2007. The pacemaker lead at issue in *Lohr* predated the SMDA, which was enacted to promote the safety and effectiveness of medical devices through the application of a more stringent or robust regulatory framework.[16] Based on the previously discussed regulations that were in place when the Avaulta products was cleared and official statements by the FDA, it is clear that both now, and at the time the Avaulta products were cleared, the 510(k) process involved a safety and efficacy determination.

Plaintiffs also incorrectly argue that evidence of the FDA's lack of enforcement action should be barred because any such suggestion would impermissibly invite the jury to speculate as to what the FDA intended or what the employees were thinking. (*See* Motion at 6.) Under Plaintiffs' reasoning, neither party would ever be able to introduce evidence of action or inaction taken by the FDA because such evidence would require the jury to consider the FDA's motivation for taking that action. However, the jurors are perfectly capable of drawing their own inferences as to why the FDA believed that no enforcement action was necessary. Given the FDA's broad enforcement authority and the fact that the FDA was closely monitoring pelvic mesh devices—as evidenced by the 2008 Public Health Notification—it would also be reasonable for jurors to conclude that the FDA"s failure to take any enforcement action was due to the fact that Bard never violated FDA regulations.[17] Thus, in this case, lack of regulatory

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[15] The Court in *Buckman* described the 510(k) process as a "comprehensive scheme" that "imposes upon applicants a variety of requirements" and necessitates submission of a wide variety of information. *Id*. at 348-50.

[16] *See* Ralph F. Hall and Michelle Mercer, "Rethinking *Lohr*: Does "SE" Mean Safe and Effective, Substantially Equivalent, or Both?", 13 MINN. J. L. SCI. & TECH. 737, 772-73 (2012).

[17] Notably, Plaintiffs' regulatory expert witness stated that when he was Commissioner of the FDA enforcement was a critical element of the FDA, and "the FDA will not hesitate to take appropriate action if [medical device companies] fail to do what is required of them." *See* David A. Kessler, M.D. Hastings Lecture (Dec. 10, 1993) available on the FDA website at http://www.fda.gov/NewsEvents/Speeches/SpeechArchives/ucm106911.htm (last accessed June 10, 2013).

action by the FDA is evidence that Bard complied with FDA regulations, the product was safe and effective, and Bard's conduct was not the type for which punitive damages are appropriate.

Finally, Plaintiffs' reliance on a pretrial oral ruling issued in a case in the *Mentor ObTape* MDL is not only easily distinguishable due to product and jurisdictional differences, but also entirely omits the key fact that in the most recent trial in the *Mentor* MDL the same court ultimately allowed the manufacturer to present evidence of its compliance with the 510(k) process. In fact, the court explicitly instructed the jury "You may consider the FDA's 510(k) process, along with all other evidence presented during the trial, in evaluating whether Plaintiff has proven her claims in this case."[18] Accordingly, evidence of Bard's compliance with the FDA's 510(k) process and post-market FDA regulations is both relevant and admissible.

III. EVIDENCE RELATED TO THE FDA'S § 510(K) PROCESS AND ENFORCEMENT ACTIONS WILL NOT UNFAIRLY PREJUDICE PLAINTIFFS.

Here, the potential for prejudice lies in excluding § 510(k) evidence, *not* in admitting it. The fact that the FDA extensively regulates medical devices is common knowledge, and jurors expect to hear whether a device has received FDA review. By stripping Bard of its ability to discuss the FDA—while Plaintiffs openly criticize how Bard brought its Avaulta products to market—a jury may be misled into believing that Bard sent its product to market with no regulatory oversight whatsoever. Moreover, this Court has already ruled that Plaintiffs' regulatory expert witness can offer testimony related to the FDA 510(k) framework and process and federal regulations, and Bard's actions taken with respect to the framework and process. Accordingly, it would be fundamentally unfair to allow Plaintiffs to present evidence of the 510(k) framework and federal regulations while at the same time prohibiting Bard from offering evidence of its compliance with the regulations and 510(k) process.

[18] *See Morey v. Mentor Worldwide, LLC*, No. 4:11-cv-5065, Court's Instructions to the Jury, Charge No. 11 (M.D. Ga. June 13, 2013). A true and correct copy of the court's jury instructions is annexed hereto as **Exhibit H**.

CONCLUSION

For all of the foregoing reasons, Bard requests that this Court deny Plaintiffs' Motion and allow Bard to present evidence on the 510(k) process and Bard's compliance with FDA regulations.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on June 17, 2013, I caused the foregoing document to be electronically filed with the Clerk of the Court using the CM/ECF system, which will send notification of such filing to the CM/ECF participants registered to receive service in this MDL.

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